

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ROBERT K. PRUD'HOMME, ET AL

Serial No.: **10/812,106**

Filed: **MARCH 29, 2004**

Title: **"POLYMERSOME FORMING
MATERIALS"**

§ Group Art Unit: **1712**

§ Examiner: **ZIMMER, MARC S.**

§ Atty. Docket No: **2004-IP-013477**

MAIL STOP AF
Honorable Commissioner of Patents
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Alexandria, VA 22313-1450

CERTIFICATE OF MAILING VIA EXPRESS MAIL

ATTY. DOCKET NO.: **HES 2004-IP-013477**
SER. NO.: **10/812,106**
GROUP ART UNIT: **1712**
EXAMINER: **MARC S. ZIMMER**

PURSUANT TO 37 C.F.R. § 1.10, I HEREBY CERTIFY THAT I HAVE INFORMATION AND A REASONABLE BASIS FOR BELIEF THAT THIS CORRESPONDENCE WILL BE DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS EXPRESS MAIL, POST OFFICE TO ADDRESSEE, ON THE DATE INDICATED BELOW, AND IS ADDRESSED TO:

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8/30/06

DATE

DECLARATION OF IAN ROBB PURSUANT TO 37 C.F.R. § 1.132

I, the undersigned, hereby declare and state that:

1. I am over the age of 21 years, of sound mind, and competent in all respects to make this Declaration.
2. I am an inventor of the subject matter of the above-referenced application, entitled, "Polymersome Forming Materials."
3. I have reviewed the Final Office Action for this patent application, as well as U.S. Patent Application Publication 2002/0161087 to Heitz, et al. (hereinafter "Heitz").

4. The Final Office Action shows certain claims rejected over *Heitz*. In rejecting these claims, the Final Office Action states as follows:

As the present Examiner understands the phenomena dictating the structure of amphiphilic molecules in aqueous media, two biggest considerations are (i) the relative weight contributions of the hydrophilic and hydrophobic portions and (ii) there has to be some minimum critical concentration of the polymer material in water that corresponds to the critical micelle concentration. That is to say, micelles and polymersomes are formed under the same concentration conditions, their relative quantities being influenced by other conditions such as condition (i). In this connection it is emphasized that the reference broadly contemplates polymers having a hydrophilic polymer block weight contribution (and, hence, a hydrophobic polymer weight block contribution) that is within the limits mandated by claim 56. Further, the concentration of said polymer is at least as high as, or higher than that recited in claim 59. It is also significant that the predominantly hydrophobic block and the water-soluble block are derived from the same monomers as those making up the hydrophobic block and hydrophilic block of the claimed polymersome. Taken together, these facts represent, in the Examiner's estimation, precisely the sort of extrinsic evidence that Applicant alleged to be lacking.

(Final Office Action at pages 4-5.) The Final Office Action further states:

It is Applicant's contention that a micelle structure can perhaps be said to be the default orientation for amphiphilic polymer molecules in aqueous solution. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. The Examiner has taken a reasonable position based on scientific principals that the composition taught by *Heitz* et al. inherently comprises polymersomes, possibly in admixture with micelles of the same polymer. The burden now shifts to Applicant to illustrate that this limitation is not necessarily inherent in the prior art composition.

(Final Office Action at pages 5-6.)

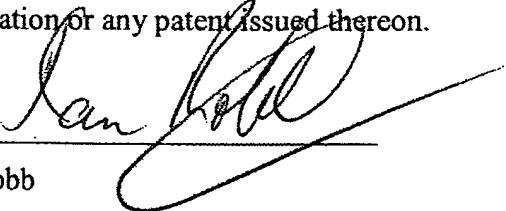
5. I respectfully disagree that my invention would be obvious in view of the prior art cited in the Final Office Action. *Heitz* is not directed to a “polymersome,” as recited by claims of the present application. Rather than disclosing the recited polymersome, *Heitz* discloses “a hydraulic fracturing fluid comprising a block copolymer containing at least one bloc water-soluble in nature and at least one block predominantly hydrophobic in nature.” *Heitz*, ¶ 12. Dependent on a variety of factors, amphiphilic molecules, such as the block copolymers disclosed in *Heitz*, may self assemble into micelles.

Generally, micelles form spontaneously when surfactants are added to water, and have been formed for centuries when washing clothing. In fact, one could use the analogy that micelles are the “default” structure when amphiphilic molecules are dispersed in water. In contrast, polymersomes are difficult to form without requiring some type of template. Polymersomes form only when the amphiphilic material is dispersed from carefully structured films (e.g. by drying a solution of the polymer in chloroform). (H. Bermudez et al, *Macromolecules* 2002, 35, 8203). The preparation of polymersomes is a recent discovery and shows that polymersomes would not be expected to form by the simple addition of copolymers to solvents, as is the case for micelles. (F. Meng et al, *Macromolecules*, 2003, 36, 3004). Furthermore, micelles have a core of hydrophobic (oily) material (there is no water in the core of such micelles). Alternatively, polymersomes have a core of aqueous solution. (A. Nikova et al, *Macromolecules*, 2004 37, 2215).

Thus, the composition of my invention comprises an element not disclosed by the prior art record. Polymersomes are difficult to form and require some type of template to be successful. The careful methods required for the preparation of polymersomes indicate that polymersome formation would not be expected by the simple addition of amphiphilic polymers to aqueous solution (as described in *Heitz*). The prior art record does not disclose any such method or template for forming polymersomes. The micelles formed in *Heitz* are not equivalent to the polymersomes of the present invention. Hence, *Heitz* does not disclose “a viscosifying agent that comprises a polymersome.”

6. In view of the foregoing, I respectfully submit that the compositions recited in the claims of my application would not be obvious to a person of ordinary skill in the art in view of the prior art of record.

7. I hereby declare that all statements made herein and of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Ian Robb

Date

8-21-06